K110895 1/3

510(k) Summary of Safety and Effectiveness

DEC 19 2011

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

NAME OF FIRM: Ortho Solutions Limited
West Station Buisness Park
Spital Road
Maldon
ESSEX, CM9 6FF
United Kingdom

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
e-mail: allippincott@msn.com

DATE: February 15, 2011

TRADE NAME: Ortho Solutions Trauma Implants for Osteosynthesis

COMMON NAME: K-Wires, Steinman Pins, Guide Pins, Fixation Pins, Rush Pins, Cerclage Wires and Cannulated Bone Screws & Washers

CLASSIFICATION: Smooth or threaded metallic bone fixation fastener (*per 21CFR888.3040*) – Pin, Fixation, Smooth; Pin, Fixation Threaded; Screw, Fixation, Bone.

Bone fixation cerclage *(per 21CFR888.3010)* – Orthopedic Wire

Single/multiple component metallic bone fixation appliance and accessories (*per 21CFR888.3030*) – Washer, Bolt Nut; Appliance, Fixation

DEVICE PRODUCT CODE: **HWC**

SUBSEQUENT PRODUCT CODE: **JDW, JDQ, HTY, HTN**

SUBSTANTIALLY EQUIVALENT DEVICES

K-Wires & Steinman Pins - Synvasive Technology (**K961522**)
K-Wires & Steinman Pins - DePuy (**K960385**)
Pins - Treu-Instrumente (**K083912**)
Orthopedic Wire - Howmedica Osteonics (**K031127**)
K-Wire - BioPro, Inc. (**K083490**)
K-Wires, Steinman Pins, Calibrated Pins -Implant Resource (**K002125**)
Rush Pin - Onyx Medical (**K903261**)
K-Wires - Medartis AG (**K092038**)
Orthopedic Wire - Osteo Technology (**K925447**)
Cann. Screws & Washers - aap Implantate AG (**K021233 & K080101**)
Cannulated Screws & Washers - I.T.S. GmbH (**K060156**)
Cannulated Screws & Washers - Wright Medical (**K100359**)
Cannulated Screws & Washers - Pioneer/Zimmer (**K102903**)
Cannulated Screws - DePuy/ACE (**K903810 & K903811**)
Cannulated Screws - Synthes (**K963172**)

K110895 2/3

DEVICE DESCRIPTION:

The *Ortho Solutions Trauma Implants for Osteosynthesis* consists of general predicate type trauma implant components commonly found with large companies with orthopedic markets in the United States. These 'general trauma implant devices' consist of the following categories:

1. K-Wires, Steinman Pins, Guide Pins, Fixation Pins, Rush Pins, and Cerclage Wire

2. Cannulated Bone Screws & Washers

A brief and concise description of each system is as follows:

1. K-Wires, Steinman Pins, Guide Pins, Fixation Pins, Rush Pins, and Cerclage Wire: These implant devices are offered in various diameters and lengths. These devices are also offered in various point configurations on one or both ends and can be partially threaded, fully threaded, smooth, or calibrated. *K-Wires, Steinman Pins and Rush Pins* position and draw fractured bone together to facilitate healing. *Guide Pins* are used to guide other implant devices into a fractured bone site area. *External Fixation Pins* are driven through the skin into bone and provide position and traction of fractured bone to allow bone healing. *Cerclage Wire* is soft to allow a 'wrap around' of fractured bones and draw fractured bone together to facilitate healing. All *K-Wires, Steinman Pins, Guide Pins, Fixation Pins, Rush Pins and Cerclage Wires* are made of surgical grade 316LVM Stainless Steel to ASTM F138 and/or 6-4 Alloyed Titanium to ASTM F136. All *K-Wires, Steinman Pins, Guide Pins, Fixation Pins, Rush Pins and Cerclage Wires* are offered 'Sterile' to the customer.

2. Cannulated Bone Screws & Washers: These implant devices consist of various length cannulated cortical and cancellous screws in a 4.0mm, 4.5mm, 5.0mm, 6.5mm, and 8.0mm thread diameter size in a full, partial, reverse-cutting, and self-tapping configurations. Washers of various sizes are matched to each screw type. Associated guide pin, drills, and ancillary instrumentation is available. The cannulated screws are intended for use over a guide pin or wire for bone fracture and bone fragment fixation. All *cannulated screws and washers* are manufactured from high strength 6-4 Alloyed Titanium to ASTM F136. All *cannulated screws and washers* are offered 'sterile' to the customer.

INTENDED USE:

The ***intended use*** of the *Ortho Solutions Trauma Implants for Osteosynthesis System* of fixation device(s) is to draw two or more aligned bone fragments together to facilitate healing.

Ortho Solutions *K-Wires, Steinman Pins, Guide Pins, Fixation Pins and Rush Pins* are indicated for use in fixation of bone fractures, for bone reconstruction, for skeletal traction in alignment of long bone fractured segments, and as guide pins & wires for insertion of implants.

K110895 3/3

Ortho Solutions *Cerclage Wire* is indicated for use for bone fracture fixation, osteotomy, arthrodesis, correction of deformity, revision procedures where other treatments or devices have been unsuccessful, and bone reconstruction procedures.

Ortho Solutions *Cannulated Bone Screws and Washers* are indicated for use over a guide pin or wire for aligned bone fracture fixation and bone fragment fixation. Washers of matching size to the cannulated bone screw may be used in certain applications.
Cannulated bone screw sizes (with optional washer) of 4.0mm, 4.5mm, 5.0mm, 6.5mm and 8.0mm are to be used with large and long bones in the skeletal anatomy. Specific indications, which are dependent in part on the diameter of the screw include: Minimally invasive fracture/joint reconstructions; Additive osteosynthesis for complex joint fractures; Multiple-fragment joint fractures; Femoral neck and femoral head fractures; Femoral supracondylar fractures; Tibial plateau fractures; Fractures of the head of the humerus & tibia; Cooper fractures of the tibia; Fractures of radius, wrist, ankle, elbow, and shoulder; Ligament fixation of the proximal humerus; Fractures of the acetabulum and dorsal pelvic ring; Condylar fractures; Ligament avulsion injuries; Malleolar and navicular fractures; Fractures of the calcaneus and talus; Arthrodesis of the ankle joint; and Avulsion fractures.

The Ortho Solutions Trauma Implants for Osteosynthesis System is not intended for spinal use.

EQUIVALENCE:

The Ortho Solutions Trauma Implants for Osteosynthesis is substantially equivalent to predicate systems from many orthopedic companies (as listed).

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Ortho Solutions Trauma Implants for Osteosynthesis are **similar** in Material, Geometry Design/Markings, and Indications to many predicate systems currently sold in the U.S. market.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The Ortho Solutions Trauma Implants for Osteosynthesis is shown to be safe and effective for use as 'sterile' and for single-use in a surgical setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC 19 2011

Ortho Solutions, LTD
% Engineering Consulting Services, Inc.
% Mr. Al Lippincott
3150 E. 200th Street
Prior Lake, Minnesota 55372

Re: K110895
Trade/Device Name: Ortho Solutions Trauma Implants for Osteosynthesis
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, HTY, JDW, HTN, JDQ
Dated: December 15, 2011
Received: December 16, 2011

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

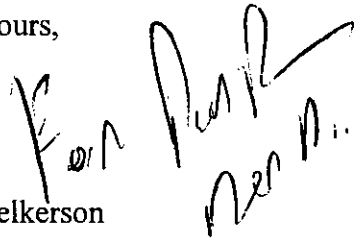
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: K110895

DEVICE NAME: **Ortho Solutions Trauma Implants for Osteosynthesis**

INDICATIONS FOR USE:

The ***intended use*** of the *Ortho Solutions Trauma Implants for Osteosynthesis System* is to draw two or more aligned bone fragments together to facilitate healing.

Ortho Solutions *K-Wires, Steinman Pins, Guide Pins, Fixation Pins, & Rush Pins* are indicated for use in fixation of bone fractures, for bone reconstruction, for skeletal traction in alignment of long bone fractured segments, and as guide pins & wires for insertion of other implants.
Ortho Solutions Cerclage Wire is indicated for use for bone fracture fixation, osteotomy, arthrodesis, correction of deformity, revision procedures where other treatments or devices have been unsuccessful, and bone reconstruction procedures.

Ortho Solutions *Cannulated Bone Screws and Washers* are indicated for use over a guide pin or wire for aligned bone fracture fixation and bone fragment fixation. Washers of matching size to the cannulated bone screw may be used in certain applications. *Cannulated bone screw sizes* (with optional washer) of 4.0mm, 4.5mm, 5.0mm, 6.5mm, and 8.0mm are to be used with large and long bones in the skeletal anatomy. Specific indications, which are dependent in part on the diameter of the screw include: Minimally invasive fracture/joint reconstructions; Additive osteosynthesis for complex joint fractures; Multiple-fragment joint fractures; Femoral neck and femoral head fractures; Femoral supracondylar fractures; Tibial plateau fractures; Fractures of the head of the humerus & tibia; Cooper fractures of the tibia; Fractures of radius, wrist, ankle, elbow, and shoulder; Ligament fixation of the proximal humerus; Fractures of the acetabulum and dorsal pelvic ring; Condylar fractures; Ligament avulsion injuries; Malleolar and navicular fractures; Fractures of the calcaneus and talus; Arthrodesis of the ankle joint; and Avulsion fractures.

The Ortho Solutions Trauma Implants for Osteosynthesis System is not intended for spinal use.

Prescription Use __X__ AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

for Mark Melkerson

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

K110895